MAY 01 2002

K012614

Medical Instruments Technology, Inc's
Reprocessed Compression Sleeve Premarket Notification

Medical Instruments Technology Inc.

Quality Reprocessing and Surgical Cost Containment Systems

Section 12: 510k Summary

I. Name of Submitter

Medical Instruments Technology, Inc.
385 North 3050 East
Saint George, UT 84790
Tel: (435) 674-4010
Fax: (435) 674-9819

Contact persons: Tom Haueter, RA/QA Manager
Crystal Batcabe, Assistant RA/QA Manager

Summary Prepared August 10, 2001

II. Device name and Classification:

Proprietary Name: N/A
Common Name: Compression Sleeve, Sleeve, Limb, Compressible
Classification: Class II per 21 CFR 870.5800 JOW

III. Predicate Device:

MIT's reprocessed compressions sleeves are substantially equivalent to:
Kendall Sequential Compression Device, Tyco Healthcare Group LP, Mansfield, MA 02048

IV. Description of Device

Compression sleeves come in 3 adjustable sizes for the leg, one size for the knee and various sizes for the foot. They are composed of either a plastic or cloth cover, over one or more plastic or rubber bladders. There are one or more plastic tubes leading from the bladder to a connector that attaches to a compressor. All work on the same principal, a compressor inflates the bladder(s) with air to squeeze the blood out of the foot or leg

and deflates to allow the blood to flow back into the foot or leg. On many of the machines, air pressure can be adjusted to allow for the length and thickness of the leg. Below is a list of the brand names and models that MIT reprocesses. Although different manufacturers originally make the devices, the intended use of the devices is identical.

V. Intended Use:

The intended use of a compression sleeve is to aid in blood circulation in bed confined patients, to prevent deep vein thrombosis and pulmonary embolism.

VI. Technological Characteristics:

MIT's reprocessed compression sleeves have the same technological characteristics as the Kendall SCD's. The materials used in the manufacture of the garments are not changed during the reprocessing process. Additionally, MIT does not change any part of the SCD that might affect its function.

Testing by MIT has shown that the reprocessed devices are substantially equivalent to the predicate in performance.

VII. Bio-Compatibility:

MIT, Inc. has provided appropriate test data to demonstrate that no biocompatibility concerns exist with sequential compression devices reprocessed using MIT's procedures.

VIII. Substantial Equivalence:

Physical Characteristics: Color, dimensions, damage

MIT compared the reprocessed compression devices to the predicate device for the parameters above. In all cases the reprocessed devices were substantially equivalent to the new devices.

Performance Characteristics: Ability to hold pressure, ability to release pressure

MIT compared the reprocessed compression devices to the predicate devices (for the parameters above) and in all cases the devices were substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 01 2002

Mr. John P. Batcabe
R & D Manager
Medical Instruments Technology, Inc.
385 North 3050 East
St. George, UT 84790

Re: K012614
Device Name: Reprocessed Compression Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 29, 2002
Received: January 30, 2002

Dear Mr. Batcabe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012614

Device Name: Reprocessed Compression Sleeves

Indications For Use:

Medical Instruments Technology, Inc's
Reprocessed Compression Sleeve Premarket Notification

Appendix 14:
Indications for Use Statement

The intended use of a compression sleeve is to increase venous blood flow in bed-confined patients, to prevent deep vein thrombosis and pulmonary embolism.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012614

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)